

REMARKS

In the Office Action, the Examiner rejected claims 22-54. Claims 44, 46, 48, 50, and 54 have been amended. Claims 22-54 remain pending in the present application and are believed to be in condition for allowance. In view of the following remarks, the Applicants respectfully request reconsideration and allowance of all pending claims.

Objection to the Claims

In the Office Action, the Examiner objected to claims 44, 46, 48, and 50 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Although Applicants do not necessarily agree with the Examiner's objection to the term "porphyrin," the Applicants amended the claims as set forth above.

However, insofar as the Examiner has objected to the terms "carbazole" and "ellipticine," the Applicants note that the Examiner has incorrectly characterized these terms. In objecting to the claims, the Examiner has erroneously stated that "As such, intercalating moiety of claim 22 or 32 appears to be a bicyclic aromatic ring system..." Office Action, p. 2. In fact, claims 22 and 32 do **not** limit the intercalating moiety to a bicyclic aromatic ring system. Claims 22 and 32 recite "the intercalating moiety comprises at least one unsubstituted aromatic ring that shares two carbons with only one other aromatic ring." The Applicants note that such a recitation in no way limits the intercalating moiety to a bicyclic structure. While the limitation recites that the unsubstituted aromatic ring shares carbons with only one other aromatic ring, this does not limit the number of rings with which the other aromatic ring may be associated.

In determining whether ellipticine falls within and properly limits claims 22 and 32, the Examiner must consider whether ellipticine contains at least one unsubstituted aromatic ring that shares two carbons with only one other aromatic ring. The structure of ellipticine (attached as Appendix A) contains a terminal unsubstituted aromatic ring (i.e., the ring including carbon 1) that shares two carbons with only one other aromatic ring. Clearly, the terminal ring is unsubstituted. The terminal ring of ellipticine and the ring with which it shares two carbons satisfy the Hückel $4n+2$ rule, which predicts whether planar rings have aromatic properties. More specifically, the terminal ring and its adjacent ring each have 6π electrons. Accordingly, ellipticine satisfies the requirement of an aromatic ring that shares two carbons with only one other aromatic ring. As such, this 4-ring structure falls within all claim limitations of claims 22 and 32.

Similarly, carbazole falls within and properly limits claims 22 and 32. Carbazole, a 3-ring structure, contains a terminal unsubstituted ring that shares two carbons with only one other ring. See Appendix B. In carbazole, either terminal ring satisfies the limitation of unsubstituted aromatic ring that shares two carbons with only one other aromatic ring. As such, carbazole has two unsubstituted rings that share two carbons with only one other aromatic ring. All three rings of carbazole satisfy the Hückel $4n+2$ rule because each of the three rings has 6 π electrons (in the middle ring, two of the π electrons are contributed by the nitrogen). Accordingly, the Applicants note that bicyclic and non-bicyclic structures may satisfy the limitation in question. In view of the amendment and remarks, the Applicants respectfully request the Examiner withdraw the objection to the claims.

Claim Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claim 54 under 35 U.S.C. § 112, Second Paragraph as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. Although Applicants do not necessarily agree with the Examiner's objection, the Applicants amended the claims as set forth above. More specifically, the amendments clarify that the box labeled "intercalating moiety" is merely a tag and not drawn to show specific bond structures. In view of the amendment, the Applicants respectfully request the Examiner withdraw the rejection to claim 54.

Claim Rejections under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 22-54 under 35 U.S.C. § 112, First Paragraph for failing to comply with the written description requirement, namely for allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Applicants respectfully traverse this rejection.

Legal Precedent and Guidelines

Regarding the written description requirement, the initial burden of proof regarding the sufficiency of the written description falls on the Examiner. See *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976); see M.P.E.P. § 2163.04. Accordingly, the Examiner must present evidence or reasons why persons skilled in the art would not recognize a description of the claimed subject matter in the applicant's disclosure. *Id.* 541 F.2d at 262, 191

U.S.P.Q. at 96. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989); M.P.E.P. § 2163.02. The examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention. See M.P.E.P. § 2163, II, A, 2. The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement. See M.P.E.P. § 2163.02. In other words, the written description requirement does not require the claims to recite the same terminology used in the disclosure. The patentee may be his own lexicographer. *Ellipse Corp. v. Ford Motor Co.*, 171 U.S.P.Q. 513 (7th Cir. 1971), *aff'd*. 613 F.2d 775 (7th Cir. 1979), *cert. denied*, 446 U.S. 939 (1980). The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. 112, first paragraph, for lack of adequate written description. See M.P.E.P. § 2163, II, A, 1. Information which is well known in the art need not be described in detail in the specification. See *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); see M.P.E.P. § 2163, II, A, 2. By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. See M.P.E.P. § 2163.07(a). Moreover, any information contained in any part of the application as filed, including the specification, claims and drawings, may be added to other portions of the application without introducing new matter. Accordingly, if an application as originally filed contains a claim disclosing material not disclosed in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno*, 768 F.2d 1340, 226 U.S.P.Q. 683 (Fed. Cir. 1985).

The pending claims fulfill the written description requirement under the Enzo test

In rejecting the claims, the Examiner stated that:

The specification teaches (page 4, paragraph 0011) that specific intercalating moieties of the invention include, but are not limited to, aromatic molecules with an intercalative binding affinity for double stranded DNA. The specification further teaches (page 5, paragraph 0011) that examples of such aromatic compounds are compounds containing, for example, acridine, porphyrin,

ellipticine, phenantroline, carbazole, benximidazole or compound with known cytostatic activity (for example antibiotics from the class of tetracyclines (anthracyclines)) such as daunorubicine, epirubicine, or mixoxantrone. Moreover, the specification further provides a structural representation of an intercalating moiety shown in figure 2. Thus, while the specification reasonably conveys three species of intercalating moieties which fit the claimed limitations selected from the group consisting of acridine, benzimidazole, and phenanthroline, the specification does not appear to be commensurate with full scope of intercalating moieties.

Office Action p. 4.

The Examiner has erred in stating that the specification does not provide adequate written description for the pending claims. The Examiner has asserted that "the specification does not appear to be commensurate with the full scope of intercalating moieties." Office Action, p. 4. However, this is not the issue at hand. The Examiner must consider instead whether the specification provides adequate written description for an intercalating moiety that "comprises at least one unsubstituted aromatic ring that shares two carbons with only one other aromatic ring, and is configured to insert into the structure of deoxyribonucleic acid, and wherein the intercalating moiety is functionalized with a ligand configured to coordinate a [metal(CO)₃]⁺ moiety." The Examiner cannot simply ignore limitations present in independent claims 22, 32, 42, and 51 in determining whether the specification provides adequate written description for the full scope of the pending claims. The invention is, for purposes of the "written description" inquiry, whatever is now claimed. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555 (emphasis added).

Further, by erroneously requiring that the pending claims fulfill the written description requirement for the genus of "intercalating moieties" without considering the structural limitations present in independent claims 22, 32, 42, and 51 that further limit this term, the Examiner has not properly applied the *Enzo* standard for written description. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316. Under *Enzo*, the test for adequate written description was laid out as consisting of either 1) a representative number of species, or 2) relevant identifying characteristics, such as as complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

A proper consideration of the written description supporting claims 22-58 should involve an examination of whether either the first prong or the second prong of the *Enzo* standard is satisfied. Turning to the limitation at hand, clearly, the recitation that the intercalating moiety "comprises at least one unsubstituted aromatic ring that shares two carbons with only one other aromatic ring, and is configured to insert into the structure of deoxyribonucleic acid, and wherein the intercalating moiety is functionalized with a ligand configured to coordinate a $[\text{metal}(\text{CO})_3]^+$ moiety" provides not only complete or partial structure of an intercalating moiety, i.e., that the intercalating moiety comprises at least one unsubstituted aromatic ring that shares two carbons with only one other aromatic ring as well as a ligand configured to coordinate a $[\text{metal}(\text{CO})_3]^+$ moiety, but also combines the structure with a known or disclosed function, i.e., the function is to insert into the structure of deoxyribonucleic acid. Turning to the specification, the specification discloses at least five representative species of compounds, e.g., acridine, ellipticine, phenanthroline, carbazole, and benzimidazole, that satisfy the limitations of the intercalating moiety. See paragraph [0011]. In addition, the specification discloses a correlation between the intercalating function and the structure. "To provide a strong intercalation, the intercalator should be preferably planar and aromatic heterocyclic." Specification, paragraph [0033]. Because the Applicants have disclosed a representative number of species as well as provided at least a partial structure and a know or disclosed function of the genus at issue, the Applicants have clearly met the *Enzo* standard.

Because the Applicants have demonstrated that the full scope of the claims is adequately described, withdrawal of the rejection of claims 22-54 under 35 U.S.C. § 112, First Paragraph, is respectfully requested.

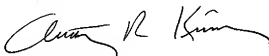
Conclusion

In view of the remarks set forth above, Applicants respectfully request reconsideration of the Examiner's rejections and allowance of all pending claims. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

General Authorization for Extensions of Time

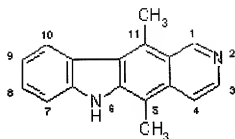
The Commissioner is hereby authorized to charge Deposit Account No. 13-1160, should any fees be due at this time.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Anthony R. Kirney", written in a cursive style.

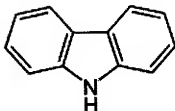
Anthony R. Kirney, Reg. No. 44,834
COVIDIEN
675 McDonnell Boulevard
Hazelwood, Missouri 63042
(314) 654-3960

APPENDIX A



Ellipticine (5,11-Dimethyl-6H-pyrido[4,3-b]carbazole)

APPENDIX B



Carbazole